DETAILED ACTION

Claims 1-19 are cancelled. Claims 20-43 are pending.
Claims 20-29, 31, 35 and 36 are withdrawn from examination as detailed below.
Claims 30, 32-34, and 37-43 are examined on the merits.

This Office Action is in reply to Applicants' correspondence of 02/05/2009 (the Remarks traversing the rejections of claims as set forth in the Office Action of 08/05/2008) and the submission (i.e. Sequence Listing and replacement Drawings) of 02/12/2010.

Applicants' remarks and amendments have been fully and carefully considered but are not found to be sufficient to put the application in condition for allowance. Any new grounds of rejection presented in this Office Action are necessitated by Applicants' amendments. Any rejections or objections not reiterated herein have been withdrawn in light of the amendments to the claims or as discussed in this Office Action.

This Action is made **FINAL**.

Please note: The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Claim Objections

1. The objections to claims 37 and 42, as set forth on page 2 of the Office Action of 08/05/2008, are **WITHDRAWN** in light of the amendments to the claims.

New Claim Objections

2. Claim 30 is objected to over recitation of phrase "or to the following fragments", as recited in lines 3-4 of claim 30. With amendment of claim 30 to remove the phrase 'corresponds to' the word 'to; in the phrase "or to the following fragments" should also be removed.

Withdrawn Objection to the Specification – Sequence Compliance Acceptance of the Drawings Submitted 02/12/2010

3. The drawings were received on 02/12/2010. These drawings are accepted. The objection to the specification for failure to comply with the sequence rules, as set forth on page 3 of the Office Action of 08/05/2008, is **WITHDRAWN** in light of the entered Sequence Listing of 02/12/2010 and the newly submitted Drawings.

Withdrawn Claim Rejections - 35 USC § 101 - Product of Nature

4. The rejection of claims 30, 32, 33 under 35 U.S.C. 101, as set forth on pages 3-4 of the Office Action of 08/05/2008, is **WITHDRAWN** in light of the amendments to the claims.

Withdrawn Claim Rejections - 35 USC § 112 2nd ¶ - Indefiniteness

5. The rejection of claims 32 and 34 under 35 U.S.C. 112, second paragraph, as set forth on pages 4-5 of the Office Action of 08/05/2008, is **WITHDRAWN** in light of the amendments to the claims.

Maintained Claim Rejections - 35 USC § 102

In the rejection of claims in view of the prior art, the breadth of the claims is noted.

Claim 30 is broadly drawn to a nucleotide sequence comprises any of: (i) the bovine *si* gene of SEQ ID NO: 3 (where the term 'represented by' does not any specific nucleotide content); (ii) a fragment containing the nucleotides situated in positions 82 to 93 of the sequence SEQ ID NO: 3 (where the limitation requires only the nucleotides (i.e. the particular monomers of the recited positions) and does not require, for example the nucleotide sequence as set forth in positions 82-93 of SEQ ID NO: 3).

Claim 32 encompasses nucleotide sequences of any sequence (i.e. any sequence derived from SEQ ID NO: 10 or 11 by the suppression and/or substitution and/or addition of on or more nucleotides) with the broad limitation that the claimed nucleic acid sequence is capable of being hybridized with any part (i.e. as little as a

single nucleotide) of a sequence delimited by positions 9 and 38 or 276 and 302 of SEQ ID NO: 3.

The primers of the primer pair of claim 33 are limited only in that they comprise approximately 10 to approximately 30 nucleotides. The primers are hybridized to sequences broadly required to be of approximately 10 to approximately 30 nucleotides and complementary to positions 1-60 of SEQ ID NO: 3, and the sequence between positions 94 to the last of the nucleotides of SEQ ID NO: 3. The primers of claim 34 (where claim 34 depends from claim 33) encompass primers hybridized to nucleic acid sequences with the same breadth as the limitations of claim 32, as addressed above.

The kit of claim 37 requires primers with the same broad structural limitations as those set forth in claim 33, as addressed above. Furthermore it is noted that the intended use of the claimed kit, as set forth in the preamble, as 'for the identification of populations or breed of ruminant animals' is not given patentable weight in the examination of the required structural limitations of the claimed kit in view of the prior art. As noted in the MPEP 211.02:

> 'a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone'.

Further, in Pitney Bowes Inc. v. Hewlett-Packard Co., 182F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999) the court held that if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, 'then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation'. Further regarding the limitations of claim 37, it is noted that the in the recitation 'and if appropriate the reagents necessary for the implementation of the amplification reaction of the number of copies of the different allelic forms of the *SILVER* gene' the phrase 'and if appropriate' indicates that 'the reagents necessary for the implementation of the amplification reaction of the number of copies of the different allelic forms of the *SILVER* gene' are optional and not a requirement for the claimed kit.

Claims 38-43 are drawn to isolated nucleic acid sequences which are limited to, for example in claim 38, comprising the nucleotides 82-93 of SEQ ID NO: 3. The limitations of the claims require only the nucleotides (i.e. the particular monomers) of the various recited positions. The claims thus do not require a particular sequence of nucleotides. For example, where the claims require that a sequence comprises the nucleotides of SEQ ID NO: 3, the limitation requires only that the claimed sequence comprises A, C, G, and T nucleotides.

6. Claims 30, 32, 33, and 38-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Maresh et al (1994).

Maresh et al teaches the analysis of the cDNA sequence encoding the human ME20 antigen. Considering the breadth of the claim limitations, as detailed earlier in this Office Action, the nucleic acids of Maresh et al anticipates the rejected claims.

Regarding claim 30, Maresh et al teaches a nucleotide sequence of the human ME20 cDNA (Fig 2A), where the sequence is comprised of A, C, G, and T nucleotides. Thus the sequence of Fig 2A of Maresh corresponds to a fragment of approximately 10 nucleotides containing the nucleotides situated in positions 82 to 93 of the sequence of SEQ ID NO: 3 (e.g. the sequence of Maresh contains the 10mer 5'-CTCGAGATGG-3' at positions 1-10 of Fig 2A, which is comprised of the nucleotides A, C, G, and T).

Regarding claim 32, Maresh et al teaches (p.88 – Cloning of ME20 antigen by polymerase chain reaction; Fig 2A) an oligonucleotide 5'-GCG TCT AGA CTC GAG ATG GAT CTG GTG CTA AAA AGA TGC CTT C-3' that is used to amplify the cDNA of Fig 2A. Relevant to the limitations of claim 32, the aforementioned oligonucleotide of Maresh et al is derived from the sequence as set forth in SEQ ID NO: 10 by substitution of the nucleotide sequence from position 1 to position 20 of SEQ ID NO: 10 with the nucleotide sequence from position 1 to position 14 of the of the oligonucleotide of Maresh et al, and the addition the nucleotide sequence 5'-GTG CTA AAA AGA TGC CTT C-3' to the 3—end of sequence of SEQ ID NO: 10. While the limitation that the derived sequence is hybridized to a nucleotide sequence has been addressed previously in this Office Action under 35 USC 112 2nd ¶, the oligonucleotide of Maresh et al is used in a polymerase chain reaction, wherein the primer is hybridized to its complementary sequence, where its complementary sequence includes 5'-

AGATCCATC-3' (i.e. complementary to positions 15-23 of the oligonucleotide of Maresh et al) and that complementary sequence is also the complement of the sequence set forth in SEQ ID NO: 3 between positions 30 and 38. Thus in the PCR of Maresh et al the disclosed oligonucleotide satisfies the broad structural limitations of the claimed nucleotide sequence, and is hybridized to part of the nucleotide sequence complementary to the nucleotide sequence delimited by the nucleotides situated in positions 9 and 38 of SEQ ID NO: 3.

With regard to the claimed primer pair of claims 33 and 37, Maresh et al teaches PCR amplification of the ME20 cDNA of Figure 2A using a first primer 5'-GCG TCT AGA CTC GAG ATG GAT CTG GTG CTA AAA AGA TGC CTT C-3' and a second primer 5'-GTA TTA GCG GCG GCA ATC ACA GCA TCA TAT GAG AGC TC-3'. During the PCR amplification of the cDNA the aforementioned primers are hybridized to their complementary sequences on opposite strand templates and extended to the end of the template, where the extended primer is itself a primer that comprises (i.e. may have any amount of any additional elements, including additional nucleotides) approximately 10 to approximately 30 nucleotides. Relevant to the limitation that one of the claimed primers is hybridized with a sequence of approximately 10 to approximately 30 nucleotides comprised in the nucleotide sequence complementary the sequence delimited by the nucleotides situated in positions 1 and approximately 60 of the nucleotide sequence of SEQ ID NO: 3, the first primer hybridizes to its complementary sequence including 5'-AGCACCAGATCCATC-3' (i.e. the complement of positions 15-29 of the first primer of Maresh et al), where the sequence is the complement of the sequence of positions 30-

44 of SEQ ID NO: 3. Relevant to the limitation that one of the claimed primers is hybridized with a sequence of approximately 10 to approximately 30 nucleotides comprised between the nucleotide situated in positions 94 and the last of the nucleotides of SEQ ID NO: 3, the extended second primer hybridizes to the sequence of Fig 2A of Maresh et al including 5'-GACTGGCTTGGTGTCTCAAGGCA-3' (i.e. positions 97-119 of the cDNA of Maresh et al), where the sequence is identical to the sequence of positions 2340-2362 of SEQ ID NO: 3. Relevant to claim 37, Maresh et al teaches a collection of nucleic acids, which is a kit (where it is noted that the specification sets forth no limiting definition regarding what is required for any collection of reagents to be a kit). The limitations of the primer pair of the kit of claim 37 are the same as the primer pair of claim 33, which have been addressed.

Regarding claims 38-43, as addressed previously, the language of the claims requires only that the claimed nucleotide sequences comprise (i.e. claims 38-40) and consist (claims 41-43) of the nucleotides of various portions of SEQ ID NO: 3. As the limitations of the claims address only the nucleotides (i.e. the monomers) of the recited positions of SEQ ID NO: 3, and do not require any particular contiguous sequence from SEQ ID NO: 3, the cDNA sequence of Maresh et al (Fig 2A) satisfies the limitations of the rejected claims as the sequence of Maresh et al is composed of the nucleotides A, C, G, and T, where the same nucleotides are in SEQ ID NO: 3 as recited in the claims.

7. Claims 30, 32, and 38-43 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank GI 412525 (1993).

Regarding claim 30, GenBank GI 412525 teaches a nucleotide sequence of a 99bp DNA where the sequence is comprised of A, C, G, and T nucleotides. Thus the sequence of GenBank GI 412525 corresponds to a fragment of approximately 10 nucleotides containing the nucleotides situated in positions 82 to 93 of the sequence of SEQ ID NO: 3 (e.g. the sequence of GenBank GI 412525 contains the 12mer 5'-TTCTGCTGTAA-3' at positions 17-28, which is comprised of the nucleotides A, C, G, and T). While the examiner has set forth that the claim does not require the contiguous nucleotide sequence as set forth in positions 82-93 of SEQ ID NO: 3, in the interest of customer service and compact prosecution it is noted that aforementioned 12mer is in fact identical to positions 82-93 of SEQ ID NO: 3.

Regarding claim 32, GenBank GI 412525 teaches a DNA sequence of 99 nucleotides that, relevant to the breadth of the limitations of claim 32, is derived from the sequence as set forth in SEQ ID NO: 10 by substitution of the nucleotide sequence from position 1 to position 30 of SEQ ID NO: 10 with the nucleotide sequence as set forth in GenBank GI 412525. While the limitation that the derived sequence is hybridized to a nucleotide sequence has been addressed previously in this Office Action under 35 USC 112 2nd ¶, the sequence of GenBank GI 412525 is a double stranded DNA sequence (i.e. the reference indicates it is 99bp, thus base paried) thus hybridized to its complementary sequence, where its complementary sequence includes 5'-TTCTT-3' (i.e. complementary to positions 28-32 of GenBank GI 412525) and that complementary sequence is also the complement of the sequence set forth in SEQ ID

NO: 3 between positions 21-25. Thus the 99bp DNA molecule of GenBank GI 412525 satisfies the broad structural limitations of the claimed nucleotide sequence.

Regarding claims 38-43, as addressed previously, the language of the claims requires only that the claimed nucleotide sequences comprise (i.e. claims 38-40) and consist (claims 41-43) of the nucleotides of various portions of SEQ ID NO: 3. As the limitations of the claims address only the nucleotides (i.e. the monomers) of the recited positions of SEQ ID NO: 3, and do not require any particular contiguous sequence from SEQ ID NO: 3, the DNA sequence of GenBank GI 412525 satisfies the limitations of the rejected claims as the sequence of GenBank GI 412525 is composed of the nucleotides A, C, G, and T, where the same nucleotides are in SEQ ID NO: 3 as recited in the claims. As detailed above, while the examiner has set forth that the claim does not require the contiguous nucleotide sequence as set forth in positions 82-93 of SEQ ID NO: 3, in the interest of customer service and compact prosecution it is noted that 12mer 5'-TTCTGCTGTAA-3' at positions 17-28 of GenBank GI 412525 is in fact identical to positions 82-93 of SEQ ID NO: 3.

Response to Remarks

Applicants have traversed the rejections of claims in view of the teachings of the prior art. Applicants' arguments (pages 18-21 of the Remarks of 02/05/2009) have been fully and carefully considered but are not found to be persuasive to withdraw the rejections. The Examiner maintains that the claims nucleic acids have considerable breadth, as set forth in the introduction to the above rejections, beyond what is argued

by Applicants. For example, while Applicants argue (p.19 of Remarks) that the claims contain the transitional phrase 'comprising', and thus require a particular nucleotide sequence of recited SEQ ID NOs, this argument is not persuasive in light of the breadth of the recited claim limitations that include, as recited for example in claim 32, any sequence derived from SEQ ID NO: 10 by deletion, substitution, or addition of one or more nucleotides. Similarly, where Applicants argue that claims 30, 38, and 42 require the 12-mer sequence set forth in positions 82-93 of SEQ ID NO: 3, such an interpretation is not consistent with the recited claim limitations of claim 30, which specifically recites a lower limit of "approximately 10" nucleotides. Thus it appears for the language of the claims that Applicants do not intend for the claimed nucleic acids to require the 12-mer sequence as argued.

As such, based on the broadest reasonable interpretation of the claims as written, the rejections as set forth above are **MAINTAINED.**

Maintained Claim Rejections - 35 USC § 103

8. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maresh et al (1994) in view of Sarka et al (1997).

Maresh et al teaches PCR amplification of the ME20 cDNA of Figure 2A using a first primer 5'-GCG TCT AGA CTC GAG ATG GAT CTG GTG CTA AAA AGA TGC CTT C-3' and a second primer 5'-GTA TTA GCG GCG GCA ATC ACA GCA TCA TAT GAG AGC TC-3'. During the PCR amplification of the cDNA the aforementioned primers are hybridized to their complementary sequences on opposite strand templates and

extended to the end of the template, where the extended primer is itself a primer that comprises (i.e. may have any amount of any additional elements, including additional nucleotides) approximately 10 to approximately 30 nucleotides. Furthermore, the first primer hybridizes to its complementary sequence including 5'-AGCACCAGATCCATC-3' (i.e. the complement of positions 15-29 of the first primer of Maresh et al), where the sequence is the complement of the sequence of positions 30-44 of SEQ ID NO: 3. Additionally the extended second primer hybridizes to the sequence of Fig 2A of Maresh et al including 5'-GACTGGCTTGGTGTCTCAAGGCA-3' (i.e. positions 97-119 of the cDNA of Maresh et al), where the sequence is identical to the sequence of positions 2340-2362 of SEQ ID NO: 3. Thus Maresh et al teaches all of the limitations of claim 33, from which rejected claim 34 depends.

Regarding the limitations of rejected claim 34, the nucleic acids taught by Maresh et al, as detailed above satisfy the broad limitations of the nucleotide sequence requirements of the claim. For example, the first oligonucleotide 5'-GCG TCT AGA CTC GAG ATG GAT CTG GTG CTA AAA AGA TGC CTT C-3' that is used to amplify the cDNA of Fig 2A is derived from the sequence as set forth in SEQ ID NO: 10 by substitution of the nucleotide sequence from position 1 to position 20 of SEQ ID NO: 10 with the nucleotide sequence from position 1 to position 14 of the of the oligonucleotide of Maresh et al, and the addition the nucleotide sequence 5'-GTG CTA AAA AGA TGC CTT C-3' to the 3—end of sequence of SEQ ID NO: 10. While the limitation that a derived sequence is hybridized to a nucleotide sequence has been addressed previously in this Office Action under 35 USC 112 2nd ¶, the first oligonucleotide of

Maresh et al is used in a polymerase chain reaction, wherein the primer is hybridized to its complementary sequence, where its complementary sequence includes 5'-AGATCCATC-3' (i.e. complementary to positions 15-23 of the oligonucleotide of Maresh et al) and that complementary sequence is also the complement of the sequence set forth in SEQ ID NO: 3 between positions 30 and 38. Additionally, the extended second primer of Maresh et al is derived from the sequence as set forth in SEQ ID NO: 11 by substitution of the nucleotide sequence from position 1 to position 30 of SEQ ID NO: 11 with the complement of the nucleotide sequence of the Fig2A of Maresh et al, and the extended primer hybridizes to the sequence of Fig 2A of Maresh et al including the sequence 5'-TTGG-3' (i.e. positions 104-107 of the cDNA of Maresh et al), where the sequence 5'-TTGG-3' is identical to the sequence of positions 294-297 of SEQ ID NO: 3.

Thus in the nucleic acids of the PCR of Maresh et al satisfy the broad structural limitations of the claimed primer pair of rejected claim 34. Furthermore the nucleic acids are hybridized to part of the nucleotide sequence complementary to the nucleotide sequence delimited by the nucleotides situated in positions 9 and 38 of SEQ ID NO: 3 (i.e. the first primer of Maresh et al), and hybridized to part of the nucleotide sequence delimited by the nucleotides situated in positions 276 and 302 of SEQ ID NO: 3.

Maresh et al does not teach that that a primer is labeled.

However, the labeled nucleic acid primers were well known in the art at the time the invention was made.

Sarkar et al teaches a radioactively labeled primer as part of a primer pair used for sequencing a PCR product (Fig 1; p.272 – Direct sequencing by SECS).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have radioactively labeled the first primer of Maresh et al, as taught by Sarkar et al, and used the labeled primer in the primer pair as taught by Maresh et al to perform sequence analysis by SECS as taught by Sarkar et al. One would have been motivated to label the primer of Maresh et al and use it in the sequencing methods of Sarkar et al, which would result in the required primer pair of the rejected claim, because Maresh et al teaches that the sequence of the Amplified cDNA was determined by dideoxynucleotide termination sequencing (p.88 – DNA sequence analysis of HF12-2), and Sarkar et al teaches that the methods of sequencing of Sarkar et al are based on dideoxy termination (p.272 – Direct sequencing by SECS), more efficient than alternative methods (p.274 – Application of SECS to screening projects), and should always produce better sequencing results than any conventional cycle sequencing (p.276, right col., part 16).

Response to Remarks

In so far as Applicants argue (p.21 of Remarks) that the applied secondary reference (i.e. Sarkar et al) does not remedy the alleged deficiencies of Maresh et al, the Examiner maintains that, given the breadth of the claims as set forth earlier in this Office Action, the teachings of Maresh satisfy the broad structural limitation of the independent claim.

The rejection as set forth is **MAINTAINED.**

Conclusion

9. No claim is allowable. No claim is free of the teachings of the prior art.

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached at 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Stephen Kapushoc/
Primary Examiner, Art Unit 1634